RESEARCH PAPER

# PREVALENCE AND DETERMINANTS OF ADVERSE DRUG REACTIONS AMONG PSYCHIATRIC OUTPATIENTS: A CROSS-SECTIONAL STUDY

**Nikita N Domble**[1], **Dr. Revanasiddappa Devarinti**[1*]

[1*]Department of Pharmacy Practice, KLE College of Pharmacy, Belagavi Airport Road, Basavan Kudachi, Belagavi - 591124, Karnataka, India (KLE Academy of Higher Education and Research)

[1]M. Pharm Student (Nikita N Domble) | ORCID: https://orcid.org/0009-0005-2923-8711 | Email: domblenikita87@gmail.com

[1*]Assistant Professor (Dr. Revanasiddappa Devarinti) | ORCID: https://orcid.org/0000-0001-9785-6814 | Email: siddu3pharma@gmail.com | Phone: +91 8886042417

***Corresponding Author:** Dr. Revanasiddappa Devarinti, Assistant Professor, Department of Pharmacy Practice, KLE College of Pharmacy, Belagavi Airport Road, Basavan Kudachi, Belagavi - 591124, Karnataka, India (KLE Academy of Higher Education and Research) | ORCID: https://orcid.org/0000-0001-9785-6814 | Email: siddu3pharma@gmail.com | Phone: +91 8886042417

## ABSTRACT

**Background:** Adverse drug reactions (ADRs) represent a significant challenge in psychiatric pharmacotherapy, contributing to treatment non-adherence, increased morbidity, and healthcare burden. Despite the high polypharmacy burden in psychiatric settings, data on ADR prevalence and associated determinants from resource-limited settings remain scarce.

**Objective:** To determine the prevalence of ADRs and identify the sociodemographic and clinical factors associated with ADR occurrence among psychiatric outpatients.

**Methods:** A cross-sectional study was conducted among 175 psychiatric outpatients. Data on sociodemographic characteristics, clinical profiles, medication regimens, and ADR occurrence were collected using a structured proforma. ADRs were assessed using standard pharmacovigilance tools. Statistical analysis included descriptive statistics and the Mann-Whitney U test for continuous variables. Significance was set at $p<0.05$.

**Results:** Of 175 participants, 56.6% were male and the majority (52.6%) were in the 21–40 year age group. ADRs were detected in 69 patients (39.4%). Polypharmacy (3–5 drugs) was prevalent in 68.6% of patients. Comorbidities were present in 61.1% of patients. Continuous variables including age ($p=0.221$), number of medications ($p=0.097$), and duration of illness ($p=0.130$) did not reach statistical significance as predictors of ADR occurrence, though patients experiencing ADRs had a marginally higher mean medication count (3.54 vs. 3.20).

**Conclusion:** ADRs were present in approximately two-fifths of psychiatric outpatients, highlighting a substantial pharmacovigilance need. Proactive monitoring strategies, medication review programmes, and targeted pharmacovigilance initiatives are warranted in psychiatric care settings.

**Keywords:** adverse drug reactions; psychiatric outpatients; pharmacovigilance; polypharmacy; psychotropic medications; cross-sectional study

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## 1. INTRODUCTION

Psychotropic medications are the cornerstone of management for a wide spectrum of psychiatric disorders including schizophrenia, bipolar affective disorder, major depressive disorder, and anxiety-related conditions. While these agents offer substantial therapeutic benefit, they are also associated with a considerable risk of adverse drug reactions (ADRs), which may compromise treatment adherence, patient safety, and overall clinical outcomes.[1]

ADRs are defined by the World Health Organization (WHO) as any noxious, unintended response to a medicine occurring at doses normally used for prophylaxis, diagnosis, or therapy.[2] In psychiatric settings, ADRs are particularly consequential because many psychotropic drugs have narrow therapeutic indices, require long-term use, and are frequently prescribed in combination—a phenomenon known as polypharmacy.[3]

Global estimates indicate that ADRs account for 5–7% of hospital admissions and represent one of the leading

causes of iatrogenic morbidity.[4] In psychiatry specifically, adverse effects such as extrapyramidal symptoms, metabolic syndrome, QTc prolongation, sedation, and anticholinergic effects are frequently encountered and can directly lead to treatment discontinuation.[5] Treatment non-adherence attributed to intolerable ADRs is a major driver of relapse and re-hospitalisation in chronic psychiatric conditions.[6]

Despite the magnitude of this problem, systematic pharmacovigilance data from psychiatric outpatient settings—particularly from low- and middle-income countries—remain limited. Most published literature focuses on inpatients or on specific drug classes, leaving gaps in understanding the overall ADR burden and its determinants in outpatient psychiatric populations.[7,8]

Identifying the prevalence of ADRs and the factors associated with their occurrence is essential for developing evidence-based monitoring protocols and risk-mitigation strategies. Variables such as age, sex, polypharmacy, comorbidities, and duration of illness have been suggested as potential predictors of ADR susceptibility in previous studies, though findings have been inconsistent.[9,10]

The present study was therefore conducted to determine the prevalence of ADRs and to examine the sociodemographic and clinical characteristics associated with ADR occurrence among psychiatric outpatients, with the goal of informing clinical practice and pharmacovigilance policy.

## 2. OBJECTIVES

Primary objective: To determine the prevalence of adverse drug reactions (ADRs) among psychiatric outpatients.

Secondary objectives:

(i) To describe the sociodemographic and clinical profile of psychiatric outpatients.

(ii) To examine the association between sociodemographic and clinical variables (age, number of medications, duration of illness) and ADR occurrence.

(iii) To identify potential risk factors for ADRs to inform pharmacovigilance strategies.

## 3. METHODS

### *3.1 Study Design and Setting*

A cross-sectional, observational study was conducted at a psychiatric outpatient department. The study period and specific site details were consistent with standard pharmacovigilance survey methodology. Ethical clearance was obtained from the institutional ethics committee, and written informed consent was obtained from all participants prior to enrolment.

### *3.2 Study Population*

Participants were adult psychiatric outpatients aged 18 years and above who were prescribed at least one psychotropic medication. Patients with incomplete medical records, those who refused to participate, and individuals who were unable to provide informed consent (due to acute psychosis or severe cognitive impairment without a legal guardian) were excluded. A total of 175 patients meeting the eligibility criteria were enrolled.

### *3.3 Data Collection*

Data were collected using a pre-validated structured proforma that captured sociodemographic information (age, sex, marital status, education, occupation, domicile, and family history of psychiatric illness), clinical details (diagnosis, comorbidities, duration of illness), and pharmacotherapy data (number and type of medications prescribed). ADR occurrence was assessed through patient interview, clinician review, and case record examination. ADRs were documented and, where applicable, causality was assessed using the WHO-UMC causality scale.11

### *3.4 Outcome Measures*

The primary outcome was the presence or absence of an ADR during the study period. Comorbidity burden was classified as: none, single, double, or multiple (three or more concurrent conditions). Polypharmacy was defined as the concomitant use of five or more medications.12

## 4. STATISTICAL ANALYSIS

All data were entered into Microsoft Excel and analysed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Categorical variables were summarised as frequencies and percentages. Continuous variables were assessed for normality using the Kolmogorov-Smirnov test; as data were non-normally distributed, they are presented as median with interquartile range (IQR: Q1–Q3) alongside mean and standard deviation (SD). Comparisons of continuous variables between the ADR and non-ADR groups were performed using the Mann-Whitney U test. A two-tailed p value of $<0.05$ was considered statistically significant.

## 5. RESULTS

### *5.1 Sociodemographic Characteristics*

A total of 175 psychiatric outpatients were enrolled. Males comprised 56.6% (n=99) of the cohort (Table 1). The largest age group was 21–40 years (52.6%, n=92), followed by 41–60 years (28%, n=49). Regarding domicile, 63.4% (n=111) resided in rural areas. A family history of psychiatric illness was reported by 46.9% (n=82) of participants. The most common marital status was married (53.7%, n=94). Primary education was the most prevalent educational attainment (36%, n=63), and 25.7% (n=45) were unemployed.

***Table 1. Sociodemographic characteristics of psychiatric outpatients (N=175)***

| Variable | Category | n | % |
|---|---|---|---|
| Gender | Male | 99 | 56.6% |
| | Female | 76 | 43.4% |
| Age group (years) | 18–20 | 9 | 5.1% |
| | 21–40 | 92 | 52.6% |
| | 41–60 | 49 | 28% |
| | 61–85 | 25 | 14.3% |
| Number of medications | ≤2 | 45 | 25.7% |
| | 3–5 | 120 | 68.6% |
| | >5 | 10 | 5.7% |
| Comorbidities | None | 68 | 38.9% |
| | Single | 74 | 42.3% |
| | Double | 26 | 14.9% |
| | Multiple (≥3) | 7 | 4% |
| Duration of illness | ≤1 year | 29 | 16.6% |
| | 1–10 years | 97 | 55.4% |
| | 11–20 years | 35 | 20% |
| | 21–30 years | 8 | 4.6% |
| | 31–40 years | 5 | 2.9% |
| | >40 years | 1 | 0.6% |
| ADR occurrence | No ADR | 106 | 60.6% |
| | ADR present | 69 | 39.4% |
| **Total** | | **175** | **100%** |

*SD, standard deviation.*

***Table 2. Sociodemographic (continued) characteristics of psychiatric outpatients (N=175)***

| Variable | Category | n | % |
|---|---|---|---|
| Family history of psychiatric illness | No | 93 | 53.1% |
| | Yes | 82 | 46.9% |
| Marital status | Unmarried | 66 | 37.7% |
| | Married | 94 | 53.7% |
| | Divorced | 7 | 4% |
| | Widow/Widower | 8 | 4.6% |
| Educational level | No formal education | 18 | 10.3% |
| | Primary | 63 | 36% |
| | Secondary | 56 | 32% |
| | Graduate | 34 | 19.4% |
| | Postgraduate | 4 | 2.3% |
| Domicile | Rural | 111 | 63.4% |
| | Urban | 64 | 36.6% |
| Occupation | Housewife | 49 | 28% |
| | Student | 21 | 12% |
| | Farmer | 23 | 13.1% |
| | Unemployed | 45 | 25.7% |
| | Government/Retired | 6 | 3.4% |
| | Employed | 31 | 17.7% |

### *5.2 Clinical and Pharmacotherapy Profile*

The majority of patients (55.4%, n=97) had a duration of illness between 1 and 10 years. Comorbidities were present in 61.1% (n=107) of participants; single comorbidity was most common (42.3%, n=74), followed by double comorbidity (14.9%, n=26) and multiple comorbidities (4%, n=7). With respect to polypharmacy, most patients (68.6%, n=120) were prescribed 3–5 medications concurrently.

### *5.3 Prevalence of ADRs*

ADRs were identified in 69 patients, yielding a prevalence of 39.4% (95% CI: 32.2–46.9%). The remaining 106 patients (60.6%) did not experience any ADR during the study period.

### *5.4 Clinical Characteristics According to ADR Occurrence*

Table 3 compares continuous clinical variables between patients with and without ADRs. The mean age was slightly lower in the ADR group (38.16 ± 14.87 years) compared to the non-ADR group (41.12 ± 15.77 years), though this difference was not statistically significant (p=0.221). The mean number of medications was marginally higher in the ADR group (3.54 ± 1.23) than in the non-ADR group (3.20 ± 1.28), but this also did not reach significance (p=0.097). Similarly, mean duration of illness was longer in the non-ADR group (118.13 ± 117.01 months) compared to the ADR group (86.33 ± 83.57 months), a difference that was not statistically significant (p=0.130).

***Table 3. Clinical characteristics according to ADR occurrence***

| Variable | Group | Mean | SD | Median | Q1 | Q3 | p value |
|---|---|---|---|---|---|---|---|
| Age (years) | No ADR (n=106) | 41.12 | 15.77 | 40 | 28 | 49 | 0.221 |
| | ADR (n=69) | 38.16 | 14.87 | 35 | 25 | 47 | |
| | Total (n=175) | 39.95 | 15.44 | 37 | 27 | 49 | |
| No. of medications | No ADR (n=106) | 3.20 | 1.28 | 3 | 2 | 4 | 0.097 |
| | ADR (n=69) | 3.54 | 1.23 | 3 | 3 | 4 | |
| | Total (n=175) | 3.33 | 1.27 | 3 | 2 | 4 | |
| Duration of illness (months) | No ADR (n=106) | 118.13 | 117.01 | 72 | 36 | 180 | 0.130 |
| | ADR (n=69) | 86.33 | 83.57 | 60 | 24 | 120 | |
| | Total (n=175) | 105.59 | 105.99 | 60 | 30 | 144 | |

*SD, standard deviation; Q1, first quartile; Q3, third quartile. Comparisons by Mann-Whitney U test.*

## 6. DISCUSSION

The present study identified an ADR prevalence of 39.4% among psychiatric outpatients, a finding consistent with—and at the higher end of—rates reported in comparable published studies. A multicentre prospective study by Sikdar et al. reported an ADR prevalence of approximately 15–40% in psychiatric inpatients, while outpatient studies from South Asian settings have reported figures ranging from 25 to 45%.7,13 The comparatively high prevalence in the present cohort may reflect the predominance of polypharmacy (68.6% on 3–5 drugs), the significant comorbidity burden (61.1%), and the long treatment durations observed in this population.

The predominance of male patients (56.6%) and the peak incidence in the 21–40 year age group aligns with epidemiological data on the peak onset of major psychiatric disorders such as schizophrenia and bipolar disorder.14 The high proportion of rural domicile (63.4%) and primary-level education (36%) underscores the importance of developing accessible, patient-centred pharmacovigilance systems tailored to low-literacy populations.

Although patients with ADRs had a slightly higher mean medication count (3.54 vs. 3.20) and a slightly younger mean age (38.16 vs. 41.12 years), neither association reached statistical significance (p=0.097 and p=0.221, respectively). This finding is consistent with some prior studies that did not identify polypharmacy as a statistically significant predictor of ADRs when analysed as a continuous variable,9 though the clinical trend is noteworthy and warrants investigation in larger, adequately powered studies. The unexpected finding that a shorter duration of illness was associated with ADR presence—albeit non-significantly—may reflect the higher medication adjustments and titrations characteristic of the earlier phases of psychiatric treatment.15

Comorbidities were recorded in the majority of patients (61.1%), reflecting the well-documented bidirectional relationship between psychiatric and medical disorders. Conditions such as hypertension, diabetes mellitus, and thyroid dysfunction are frequently encountered alongside psychiatric diagnoses and can alter drug pharmacokinetics and pharmacodynamics, thereby increasing ADR vulnerability.16 Systematic comorbidity screening should therefore be incorporated into routine psychiatric assessment.

The high rate of family history of psychiatric illness (46.9%) may have implications for pharmacogenomic susceptibility to ADRs, a relationship that warrants further exploration through pharmacogenetic studies in this population.17

From a public health perspective, the current findings highlight an urgent need for structured pharmacovigilance programmes within psychiatric outpatient services. These should include systematic ADR screening using validated tools, patient and caregiver education, and regular medication review—particularly for patients on polypharmacy regimens. Integration of clinical pharmacists into the outpatient psychiatric team has been shown to reduce ADR burden and improve medication management in comparable settings.[18]

## 7. LIMITATIONS

This study has several limitations. First, its cross-sectional design precludes causal inference regarding ADR determinants. Second, the specific psychiatric diagnoses, individual drug classes, and types of ADRs were not granularly analysed; future work should stratify findings

by diagnosis and drug class. Third, the relatively modest sample size may have limited statistical power to detect significant associations, particularly for the continuous variables examined. Fourth, underreporting of mild ADRs by patients cannot be excluded. Fifth, the single-centre design limits generalisability to other settings. Notwithstanding these limitations, the study provides a useful baseline estimate of ADR prevalence in this underserved population.

## 8. CONCLUSION

ADRs were detected in 39.4% of psychiatric outpatients, representing a substantial pharmacovigilance burden. While continuous clinical variables such as age, polypharmacy, and illness duration showed trends towards ADR association, these did not reach statistical significance in this cohort, possibly owing to sample size constraints. The findings underscore the necessity for systematic ADR monitoring, routine medication reconciliation, and strengthened pharmacovigilance systems in psychiatric outpatient settings. Future prospective, multicentre studies stratified by diagnosis and drug class are warranted to characterise ADR determinants more comprehensively and to guide evidence-based prescribing guidelines.

## DECLARATIONS

Conflict of interest: The authors declare no conflicts of interest.

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Ethical approval: Obtained from the Institutional Ethics Committee. All participants provided written informed consent.

Data availability: Data are available from the corresponding author upon reasonable request.

## REFERENCES

1.Salvi V, Migliarese G, Venturi V, Rossi F, Torriero S, Viganò V, et al. Adverse effects of antipsychotics in real-world practice: a cross-sectional study. *Psychiatry Res.* 2017;256:242–8. doi:10.1016/j.psychres.2017.06.051

2.World Health Organization. *The importance of pharmacovigilance: safety monitoring of medicinal products*. Geneva: WHO; 2002.

3.Mojtabai R, Olfson M. National trends in psychotropic medication polypharmacy in office-based psychiatry. *Arch Gen Psychiatry.* 2010;67(1):26–36. doi:10.1001/archgenpsychiatry.2009.175

4.Angamo MT, Chalmers L, Curtain CM, Bereznicki LRE. Adverse-drug-reaction-related hospitalisations in developed and developing countries: a review of prevalence and contributing factors. *Drug Saf.* 2016;39(9):847–57. doi:10.1007/s40264-016-0444-7

5.De Hert M, Detraux J, Peuskens J. Second-generation and newly approved antipsychotics, serum prolactin levels and sexual dysfunctions: a critical literature review. *Expert Opin Drug Saf.* 2014;13(5):605–24. doi:10.1517/14740338.2014.906579

6.Semahegn A, Torpey K, Manu A, Assefa N, Tesfaye G, Ankomah A. Psychotropic medication non-adherence and its associated factors among patients with major psychiatric disorders: a systematic review and meta-analysis. *Syst Rev.* 2020;9(1):17. doi:10.1186/s13643-020-1274-3

7.Sikdar KC, Alaghehbandan R, MacDonald D, Barrett B, Collins KD, Gadag V. Adverse drug reactions in adult patients receiving antipsychotic medications. *Pharmacoepidemiol Drug Saf.* 2010;19(1):79–88. doi:10.1002/pds.1876

8.Abubakar AR, Chedi BA, Mohammed KG, Haque M. Drug reaction reporting by health workers in Nigeria: a call for action. *J Young Pharm.* 2015;7(3):206–11. doi:10.5530/jyp.2015.3.8

9.Brahma DK, Wahlang JB, Marak MD, Ch Sangma M. Adverse drug reactions in the elderly. *J Pharmacol Pharmacother.* 2013;4(2):91–4. doi:10.4103/0976-500X.110872

10.Kongkaew C, Noyce PR, Ashcroft DM. Hospital admissions associated with adverse drug reactions: a systematic review of prospective observational studies. *Ann Pharmacother.* 2008;42(7):1017–25. doi:10.1345/aph.1L037

11.Uppsala Monitoring Centre. *The use of the WHO-UMC system for standardised case causality assessment*. Uppsala: WHO Collaborating Centre for International Drug Monitoring; 2005.

12.Masnoon N, Shakib S, Kalisch-Ellett L, Caughey GE. What is polypharmacy? A systematic review of definitions. *BMC Geriatr.* 2017;17(1):230. doi:10.1186/s12877-017-0621-2

13.Pirmohamed M, James S, Meakin S, Green C, Scott AK, Walley TJ, et al. Adverse drug reactions as cause of admission to hospital: prospective analysis of 18 820 patients. *BMJ.* 2004;329(7456):15–9. doi:10.1136/bmj.329.7456.15

14.Kessler RC, Berglund P, Demler O, Jin R, Merikangas KR, Walters EE. Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. *Arch Gen Psychiatry.* 2005;62(6):593–602. doi:10.1001/archpsyc.62.6.593

15.Charlson FJ, Ferrari AJ, Santomauro DF, Diminic S, Stockings E, Scott JG, et al. Global epidemiology and burden of schizophrenia: findings from the global burden of disease study 2016. *Schizophr Bull.* 2018;44(6):1195–203. doi:10.1093/schbul/sby058

16.De Hert M, Correll CU, Bobes J, Cetkovich-Bakmas M, Cohen D, Asai I, et al. Physical illness in patients with severe mental disorders. I. Prevalence, impact of medications and disparities in health care. *World Psychiatry.* 2011;10(1):52–77. doi:10.1002/j.2051-5545.2011.tb00014.x

17.Bousman CA, Bengesser SA, Aitchison KJ, Amare AT, Aschauer H, Baune BT, et al. Review and consensus on pharmacogenomics testing in psychiatry. *Pharmacopsychiatry.* 2021;54(1):5–17. doi:10.1055/a-1288-1061

18.Graabaek T, Kjeldsen LJ. Medication reviews by clinical pharmacists at hospitals lead to improved patient outcomes: a systematic review. *Basic Clin Pharmacol Toxicol.* 2013;112(6):359–73. doi:10.1111/bcpt.12062